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EXAMINER	
DUFFY, PATRICIA ANN	

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1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No.	Applicant(s)
	10/581,294	PAUL ET AL.
	Examiner	Art Unit
	Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3-18-2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *51,52,69,70,79,80,82-85 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-8,11-13,15-24,29,30,32-38,40-48,50-53,55-57,62,63,65-67,69-71,76-80,82-85 and 90.

Continuation of Disposition of Claims: Claims rejected are 1-8,11-13,15-19,21-23,25,29,30,32-38,40-43,45-48,50,53,55-57,62,63,65-67,71 and 76-78.

DETAILED ACTION

The Examiner and Art Unit in charge of this application has changed. Please address all future correspondence to Examiner Patricia Duffy, Art Unit 1645.

The amendment filed 3-4-2011 and the traversal response filed 5-12-2010 has been entered into the record.

The petition filed 5-11-2010 has been granted.

However, it is noted that PCT Rule 13.1 requires a special technical feature among the groups of inventions. In view of the amendment to the claims and prosecution history of the application the following new lack of unity is set forth:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
Group I , claim(s) 1-8, 11-13, 15-19, 21-23, 25, 29, 30, 32-37, 38, 40-43, 45-48, 50, 53, 55, 56, 57, 62, 63, 65, 66, 67, 71 and 76-78, drawn to the first appearing technical feature the water binding covalently reactive polypeptide antigen binding analog of formula I as set forth in claim 2, all the methods of using.

Group II, claim(s) 51 and 52, drawn to the second appearing technical feature a catalytic antibody produced by a particular process.

Group III, claims 69 and 70, as drawn to methods of using the second technical feature of the antibody of Group II.

Group IV, claims 79-80 and 82-85 and 90, as drawn to methods of use of any pCRA and do not recite the special technical feature of Group II.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups II, III and IV *a priori* lack the unity of invention with Group I, because Groups II and III are drawn to a second technical feature (an antibody), use of the antibody or as in Group IV fail to recite the use of the special technical feature of Group I as set forth above.

Inasmuch as, applicants have received an action on the merits, examination on the merits continues on Group I.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § § 1.821-1.825 because the sequences in the specification are not identified by a specific sequence identifier. Applicants are directed to amend the specification to place the relevant sequence identifier after the appropriate sequences. For example page 8 and page 36 recite sequences having four or more fixed amino acids that are not followed by an appropriate sequence identifier. Full compliance with the sequence rules is required in response to this office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, or provided by Applicants in a 1449 they have not been considered.

Rejections Withdrawn

Any objection or rejection not reiterated herein is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> A claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 1-8, 11-13, 15-19, 21-23, 25, 29, 30, 32-37, 38, 40-43, 45-48, 50, 53, 55, 56, 57, 62, 63, 65, 66, 67, 71 and 76-78 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for all the reasons made of record.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue specific embodiments and that the specification provides sufficient guidance for one of ordinary skill in the art to prepare covalently binding catalytic antibodies to an antigenic polypeptide of medical interests and that that skilled artisan could design alternatives.

It is noted that the disclosed specific peptides are limited to attachment to the lysine side chain and the specification does not teach any examples of linkers or attachments to any other amino acid in a antigenic determinant or provide for successful covalent and catalytic antibodies that bind thereto. The disclosed embodiments is not representative of the genus claimed as any amino acid, any linker any charged or neutral group any water binding group and any covalently reactive group are included by the scope of the claims. The disclosure of particular peptide derivatized at the lysine side chain functional group having a particular linker, charged/neutral group, electrophilic group and water binding group is not representative of the genus of hundreds of thousands of covalently reactive polypeptide antigen analogue (pCRA) of the claims.

Although the disclosure would put the skilled artisan in possession of different elctrophilic groups of figure 5, , the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing, which of those in combination with all the other plethora of elements would have the necessary functional

activities. The specification lacks written description of a representative number of pCRA variants to support the genus as claimed and those of ordinary skill in the art would not conclude that the Applicant was in possession of the claimed genus for all the reasons made of recod. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.). Applicants are directed to Revision I of the Written Description Training materials, posed 4/11/08: <http://www.uspto.gov/web/menu/written.pdf> and MPEP 2163.

The courts have held that possession of a genus may not be shown by merely describing how to obtain members of the claimed genus (i.e. make and test to see if they lack the requisite activity) or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895 and *In re Kubin*, 90 USPQ2d 1417 (Fed. Cir. 2009). In addition, the court has held that a method of identification of compounds (i.e. screening for functional variants) is not a description of the compounds *per se* that meet the requisite function to use in the associated methods. *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004. Finally, function does not describe a structure, because the specification does not provide relevant identifying characteristics, including functional characteristics when coupled with known or disclosed correlation between function and structure. The courts have held that in these instances, the specification lacks written description see *Enzo Biochem Inc. v. Gen-Probe Inc.* 63 USPQ2D 1609 (CAFC 2002) and *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). When the genus is large and the specification lacks

a known (art described) or disclosed correlation between structure and function, the written description of the specification does not convey possession of the claimed genus.

The rejection is maintained.

Claims 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Clams 34-36 require specific monoclonal antibody clones. The specification lacks complete deposit information for the deposit of the clone. Because it is not clear that cell lines possessing the properties of the recited clones are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims requires the use of the clones, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of the cell line producing the monoclonal antibody clones is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this

specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological

material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim 76-78 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The dictionary definition of vaccine is "A prophylactic or therapeutic material containing antigens derived from one or more pathogenic organisms which, on

administration to man or animal, will stimulate active immunity and protect against infection with these or related organism (i.e. produce protective immunity)." (The Dictionary of Immunology, Herbert et al eds, Academic Press, 1995) would clearly realize the critical deficiency of this specification with respect to vaccines. There is no demonstration of protective immunity upon administration in any animal model of disease for a pCRA prepared from pg120 as set forth in claim 78 and encompassed by claims 76 and 77.

The specification fails to teach that any immune response generated upon injection by the claimed pCRAs alone provide prophylatic antibodies for a protection against infection. Vaccines by definition trigger an immunoprotective response in the host vaccinated and mere antigenic response is insufficient. It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach even one of the claimed polypeptides or fragments thereof alone or in combination with other antigens does in fact confer protection from infection, as is requisite of a vaccine composition. The art teaches that the selection of protective antigens from the plethora of protein antigens available is unpredictable. The specification fails to teach that the claimed gp120 pCRA polypeptide or antigenic fragment thereof is able to perform as a vaccine (i.e. protection, reduction in morbidity and/or mortality of disease) and the art does not such as a vaccine.

It has been well known in the art that retroviral infections in general and HIV infections in particular, are refractory to anti-viral therapies. The obstacles to therapy of HIV are well documented in the literature. These

obstacles include: (1) the extensive genomic diversity and mutation rate associated with the HIV retrovirus, particularly with respect to the gene encoding the envelope protein; (2) the fact that modes of viral transmission include both virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert manner, as well as via free virus transmission; (3) the existence of a latent form of the virus; (4) the ability fo the virus to evade immune response in the central nervous system due to the blood-brain barrier; and (5) the complexity and variation of the pathology of HIV infection in different individuals. The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the claimed invention with a reasonable expectation of success and without undue experimentation. The courts have held that it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. (Genentech Inc. v. Novo Nordisk A/S Ltd., 42 USPQ2d 1001). Moreover, the specification must have been enabling at the time the invention was made and developments after the time of filing are of no consequence to what one skilled in the art would have believed at the time of filing (*In re Wright*, 27 USPQ2d 1510).

Further, it is well known in the art that individuals infected with HIV produce neutralizing antibodies to the virus, yet these antibodies are not protective and do not prevent the infection from progressing to its lethal conclusion. Further, as taught by Fahey et al. (Clin. Exp. Immunol., 1992), clinical trials using a variety of immunologically based therapies have not yielded successful results in the treatment and/or prevention of HIV infection (see Table 1). Hirsch et al. (N. Eng. J. Med., 1993) clearly teach that the success of translating promising avenues of investigation into clinical practice has been meager (page 1806, column 1, paragraph 2) Haynes et al. (Ann. Med., 1996) teach the major scientific obstacles blocking development of HIV vaccines (see page 40, column 1, paragraph 2). Further, Haynes et al. teach that "current animal models of either HIV or SIV fall short of precisely mirroring human HIV infection" and that "lacking these modes, researchers must turn towards human clinical trials to answer may of the difficult questions about HIV pathogenesis and HIV vaccine development" (see page 40, column 1, paragraph 3). Thus, it is clear from the evidence above and well established in the art that the ability to treat and/or to prevent HIV infection is highly unpredictable and has met with very little success. Even as late as 2008, the skilled artisan would have reason to doubt that such vaccines could be produced. **HIV vaccine may never be found, warns leading scientist Dr David Baltimore.**

Feb 14, 2008
Mark Henderson, Science Editor, in Boston

http://www.timesonline.co.uk

A simple injection to protect against AIDS is no closer today than it was when the virus that causes it was first identified in the early 1980s, one of the world's leading HIV experts said today.

Professor David Baltimore, a Nobel laureate who is President of the American Association for the Advancement of Science, told its annual conference in Boston that the failure of every promising approach to an HIV vaccine had led many scientists to wonder whether it would ever be possible to create one.

While both public and private sector researchers have done their best, HIV's unparalleled ability to evade the body's immune system has defeated current medical science, Professor Baltimore said in his presidential address to the conference.

No research projects currently underway, including his own, have any realistic prospect of producing a vaccine for at least a decade, and success may take even longer, he said. "The community is depressed because we see no hopeful route to success."

Professor Baltimore's comments are particularly significant as he is one of the foremost authorities on the HIV virus. He won his Nobel Prize in 1975 for the discovery of reverse transcriptase, a chemical enzyme that was later found to be used by HIV to reproduce in human cells.

The lack of progress suggests that for the foreseeable future, a vaccine will not be capable of playing a role in containing the global epidemic of HIV/Aids, which affects an estimated 33 million people and kills between 2.4 million and 3.3 million each year, chiefly in sub-Saharan Africa.

"It's such a sad topic," he said of the search for an Aids vaccine. "We have been trying to make an HIV vaccine since the day HIV was discovered. In 1984, we were told that as the virus had been found, a vaccine should be just around the corner. History was on our side - we have been able to make vaccines versus almost all the viruses that affect humans. But we are no closer to a vaccine now than we were then.

"Every year since then, we have been saying it is at least 10 years away. I still think it is at least 10 years away. And if it has been 10 years away for 20 years, you might ask does that really mean it will never happen? I'm not prepared to say that, because I don't want to take a pessimistic stand. This is too important to give up on.

"Our lack of success may be understandable, but it is not acceptable."

He said there was now a consensus that approaches based on stimulating antibody production - the traditional way in which vaccines work - would not be effective against HIV because of its extraordinary ability to "cloak" itself by changing its protein shell.

The general mood of pessimism was heightened last year by the failure of clinical trials of a candidate vaccine taking a different approach, made by the drug company Merck, which many researchers had considered promising.

Therefore, in the absence of a teaching of the claimed polypeptides are effective in prevention of disease, the specification is not be enabled for generation of prophylatic antibodies for antigens associated with medical conditions and HIV in particular. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claims 1-8, 11-13, 15-19, 21-23, 25, 29, 30, 32-37, 38, 40-43, 45-48, 50, 53, 55, 56, 57, 62, 63, 65, 66, 67 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and every claim dependent thereon in view of the term "covalent antibody". The specification teaches that the pCRA of Formula (I) covalently binds the antibody via the covalently reactive electrophilic group when the antibody binds the antigenic determinant (i.e. paratope). The binding of the antibody to the paratope is not covalent. As such, the use of covalent binding with respect to the antibody binding is inconsistent with the use in the art and inconsistent with the description of how the antibody binds the antigenic determinant of the pCRA. Furthermore, the method does not provide for antibodies that have both properties because the second screening step does not require that catalytic antibodies be screened from those that the pCRA covalently binds and because the "or to the peptide or protein having one or more of the antigenic determinants comprising the pCRA". The claims are also indefinite because the claims indicate that antibodies are produced, but fail to state the immunogen for their production and as such, it is unclear how antibodies are produced in the absence of an immunogen.

As to claim 1, 2 and every claim dependent thereon. The claims are indefinite in because the claims appear to be missing an element in the definition "Y' is or a linker". There appears to be a phrase or language missing.

As to claim 12, the claim fails to properly provide for antecedent basis for obtaining lymphocytes and monoclonal antibodies or fragments thereof from the organism. There is no positively recited step that provides for production of monoclonal antibodies from the organism and at what step, before producing antibodies or after ? Additionally, it is noted that "stes" is not a word and it appears to be a typographical error of "steps".

As to claim 37, the claims lack proper antecedent basis and lack method steps as the claims do not obtain DNA from any source or even an antibody and as such, insertion into a construct that is not made or does not have appropriate immunoglobulin sequences is unclear. The claims clearly lack positively recited method steps linking the methodology to each previous step in each previous claims and therefore provide for proper antecedent basis in the omission of multiple clear positively recited steps.

As to claim 38, step d is unclear because it is unclear what antibodies are purified. As to step a it is unclear what the library of cell lines or immunoglobulin fragment genes are prepared from ?? What is the relationship between step a and steps b and c, since step a never produces antibodies for screening as such it is unclear where the antibodies of steps b and c come from.

As to claim 50, the steps lack clear antecedent basis in claim 38 from which it depends. For example, the method does not limit the steps of claim 38 and lymphocytes are never obtained.

As to claim 53, the claim recites "a pCRA". "A" means any and does not require the pCRA of Formula I and as such it is unclear as to what is being referenced. Is the pCRA of claim 53, step (a) different or the same as that recited in claim 38 ?

As to claim 67 and dependent claims, the terms "the VL and VH domains" lack antecedent basis in claim 12. The term "the resultant antibody fragments" lacks clear antecedent basis in the claims as because no antibody fragments are produced. The term

Claim 12-19, 38, 41-43, 45, 46, 47, 48, 50, 53, 58, 56, 57 62, 63, 65, 67 and 76-78 are rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of the a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

See the "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications" (Federal Register, Vol. 76, No. 27, Wednesday, February 9, 2011), pg 7166, section "5. Dependent Claims", which states that "If the dependent claim does not comply the with the requirements of § 112, ¶4, the examiner should reject the dependent claim under § 112, ¶4 as unpatentable rather than objecting to the claim" and "a dependent claim must be rejected under § 112, ¶4 if it omits an element from the claim upon which it depends or it fails to add a limitation to the claim upon which it depends".

Claims 12-17 and 19 fails to properly further limit the subject matter of claim 1 from which it depends. The steps of screening and selecting are drawn to preparing cell lines, but the steps of screening and selecting use antibodies per se. As such, the method steps do not properly further limit the process of claim 1. As to claim 19, the claim fails to further limit the method because they are not monoclonal cells and claim 12 requires monoclonal antibodies.

As to claim 18, the claim fails to properly further limit the method of claim 1 as it recites recombinantly produced antibody fragments and the antibodies of claim 1 are produced in an organism. As such, the method steps of claim 18 are not found to properly further limit the method of claim 1 from which it depends.

Claim 38, 76 and dependent claims 41-43, 45, 46, 47, 48, 50, 53, 58, 56, 57 62, 63, 65, 67, 77 and 78 improperly reference the pCRA of claim 1. It is noted that claim 1 is a method and as such, claim 38 and associated dependent claims do not properly further limit the method of claim 1. Applicants should move the appropriate subject matter referenced in claim 1 into claim 38 to obviate this rejection.

As to claim 67, the claim does not further limit the method of claim 12, but recites a new goal of improving the properties of the covalent or catalytic activity of the antibodies of claim 12. As such, it fails to properly further limit the method of claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 38, 45, 46, 47, 48, 50, 53, 55, 56, 57, 62, 63, 65 and 66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Paul et al (US 6,235,714 issued May 22, 2001).

It is noted at the outset that the claims do not require binding to the pCRA of Formula I and catalysis function as all the elements of the claim are recited in the alternative.

Paul et al teach methods of obtaining catalytic antibodies, covalent antibody fragments or catalytic antibody fragments as it reads on the alternative not requiring the pCRA of Formula I.

Paul et al teach methods of obtaining catalytic and covalent Fv and VL domain immunoglobulin libraries and phage display libraries from mice and autoimmune disease mice (MRL/lpr; murine systemic Lupus Erythematosus model) and screening of antibodies that bind the reactive antigen analog of EFGR and also catalyze cleavage of the peptide. Paul et al teach purification of the recombinant fragments/antibodies with these properties at column 15, line 47 to column 22, line 15. Paul et al teach antigenic determinants forming the basis for the CRAAs are from neoplastic antigens such as EGF, prolacting metalloproteinases, receptors such as EGFR, HER-2, inflammatory mediators such as TNF, interleukins and their associated receptors, VIP, vassopressin and thyroglobulin (see columns 8-9). As such, Paul et al anticipates the claimed invention.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Gary Nickol can be reached at 571-272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner